DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
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FALLS CHURCH VA 22041-3258

REPLY TO
ATTENTION OF

MCMR-RCQ

30 November 2001

HSRRB Policy Memorandum 01-02, Version 01

SUBJECT: Witness Requirement for Informed Consent Process and Form

1. REFERENCES:

a. 32 CFR 219, *Protection of Human Subjects*

b. AR 70-25, *Use of Volunteers as Subjects of Research, 25 January 1990*

c. FDA Information Sheets, 1998 Update

d. ICH Guideline for Good Clinical Practice (1997)

e. 21 CFR 50.27, *Documentation of Informed Consent*

f. Memorandum from Mr. Stephen Maleson, for RCQ, dated 24 April 2001, titled "Witness Requirement for Informed Consent Process and Form"

2. HISTORY. This is the first version of HSRRB Policy Memorandum 01-02. This version is effective 5 December 2001. Details of the history can be found in Appendix A.

3. PURPOSE. This policy is being written to clarify the witness requirement for the informed consent process and form.

4. SCOPE. This policy affects research that requires review by The Surgeon General's Human Subjects Research Review Board (HSRRB).

5. POLICY.

a. The U.S. Army Medical Research and Materiel Command (USAMRMC) intends for its witness requirement for the informed consent process to be consistent with the requirement established by guidance and regulation from the FDA, OHRP, and ICH Guideline for GCP.

b. A witness is required to be present during the informed consent process for a potential subject only if the subject is illiterate, or if the subject is not given an

opportunity to read the informed consent document. If a legally authorized representative will be consenting on behalf of the potential subject, a witness is required only if the legally authorized representative is illiterate or not given an opportunity to read the informed consent document. In these cases, the elements of informed consent will be presented orally, and a witness must be present for the oral presentation. Written documentation in such cases is limited to a short consent form and written summary. The witness must sign both the short form and the written summary (32 CFR 219.117; 21 CFR 50.27; ICH Guideline for GCP, 4.8.9.).

c. Though a witness to the informed consent process is not required when the subject is capable of reading and understanding the consent document, the HSRRB may nevertheless use its discretion to require witness presence during the consent process for any protocol, subject, or class of subjects. For example, if the subject is a member of a "vulnerable population", the HSRRB may choose to require witness presence. Vulnerable populations include, but are not limited to, children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons (32 CFR 219.111). 32 CFR 219.111 requires "additional safeguards" to protect the welfare of these subjects; the HSRRB may feel that witness presence should be one of those additional safeguards.

d. The witness should be impartial, so the witness would be able to testify about the informed consent process with no presumption of bias. The ICH Guideline for GCP defines "Impartial Witness" in paragraph 1.26 as "[a] person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, ...". When a witness is required by the ICH Guideline for GCP, it is an "impartial" witness.

(1) The PI, associate investigators, study coordinator, and any other research staff shall be excluded from serving as witnesses. An institution employee not connected with the research, and not otherwise subject to command or supervisory influence by someone involved with the research, can serve as the witness, as can any other individual not connected with the research. The medical monitor can also serve as a witness, even though the medical monitor is connected with the research. The medical monitor's position is that of an advocate for the subject, so the presumption of bias that accompanies other research staff is effectively overcome.

(2) If a PI asserts that it is impractical to find impartial witnesses, he/she should satisfy the HSRRB that the requirement for an impartial witness is overly burdensome for the protocol (or subject) in question. If so satisfied, the HSRRB may approve protocols in which the witness is not impartial.

e. The individual conducting the consent interview may not also serve as the witness; the witness must be a third party.

f. When a witness is required, a witness must be present for the consent interview and the subject's actual signature. The subject's signature generally takes place at a later time or different day than the consent interview.

(1) It is not necessary to have the same witness present for the consent interview and the subject's signature.

(2) The language on the consent form should clearly indicate whether the witness was present for the consent interview or the subject signature. Because there are two separate events, and possibly two different witnesses, there should be two witness signature blocks. An example of acceptable language that is recommended is as follows:

Witness to Consent Interview

On the date given next to my signature, I witnessed the "Consent Interview" for the Research Study named above in this document. I attest that the information in this consent form and the written summary was explained to the subject or the subject's legally authorized representative, and the subject or subject's representative indicated that his/her questions and concerns were adequately addressed.

Name of Witness _____

Signature of Witness _____ Date _____

Witness to Subject's Signature

On the date given next to my signature, I witnessed the subject or the subject's legally authorized representative sign his/her name on this consent form.

Name of Witness _____

Signature of Witness _____ Date _____

g. If a witness is not required under this Policy, the consent form should either be without a witness signature block, or should have the witness signature block marked as "Optional" or "Not Applicable". If a protocol is using the Volunteer Agreement Affidavit (VAA) from AR 70-25, the witness signature block will have to be modified in accordance with this Policy.

h. Because there is no federal requirement for a subject or witness to initial each page of the informed consent document, HSRRB no longer requires the subject or witness to initial each page of the consent form or VAA.

Julie K. Zadinsky

Encl

JULIE K. ZADINSKY
Colonel, AN
Acting Chair, Human Subjects
Research Review Board

JP

RECOMMEND APPROVAL/~~DISAPPROVAL~~

John S. Parker DATE: 3 Dec 01

JOHN S. PARKER
Major General, MC
Chair, Human Subjects
Research Review Board

APPROVED/~~DISAPPROVED~~

FOR THE SURGEON GENERAL:

Patrick D. Sculley DATE: 5 Dec 01

PATRICK D. SCULLEY
Major General
Deputy Surgeon General

APPENDIX A
HSRRB Policy Memorandum History

Version Number: 01

Version Date: 28 November 2001

Effective Date:

Reason for Revisions: This is the initial policy.

Detailed List of Changes: N/A